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TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT
 (Under 37 CFR 1.97(b) or 1.97(c))

Docket No.
 GC22.4-CON2

In Re Application Of: **Rasmussen et al.**

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Application No.	Filing Date	Examiner	Customer No.	Group Art Unit	Confirmation No.
10/814,025	March 31, 2004	Sullivan, Daniel M.	24536	1636	4968

Title: **ENZYMATICALLY ACTIVE RECOMBINANT GLUCOCEREBROSIDASE**

Address to:
Commissioner for Patents
 P.O. Box 1450
 Alexandria, VA 22313-1450

37 CFR 1.97(b)

- The Information Disclosure Statement submitted herewith is being filed within three months of the filing of a national application other than a continued prosecution application under 37 CFR 1.53(d); within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 in an international application; before the mailing of a first Office Action on the merits, or before the mailing of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114.

37 CFR 1.97(c)

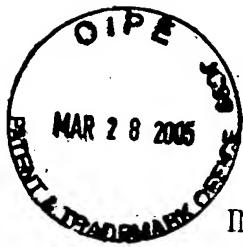
- The Information Disclosure Statement submitted herewith is being filed after the period specified in 37 CFR 1.97(b), provided that the Information Disclosure Statement is filed before the mailing date of a Final Action under 37 CFR 1.113, a Notice of Allowance under 37 CFR 1.311, or an Action that otherwise closes prosecution in the application, and is accompanied by one of:

the statement specified in 37 CFR 1.97(e);

OR

the fee set forth in 37 CFR 1.17(p).

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Docket Number: GC22.4-CON2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Rasmussen et al.

Serial No.: 10/814,025

Confirmation Number: 4968

Examiner: Sullivan, Daniel M.

Art Unit: 1636

Filed: March 31, 2004

For: ENZYMATICALLY ACTIVE RECOMBINANT
GLUCOCEREBROSIDASE

I certify that this document is being deposited on March 25, 2005 with the United States Postal Service as First Class Mail under 37.C.F.R. 1.8 and is addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Deborah A. Gunkel
Printed name of person mailing correspondence

Deborah A. Gunkel
Signature of person mailing correspondence

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §§ 1.56, 1.97 and 1.98, Applicants request consideration of this Information Disclosure Statement.

Compliance With 37 C.F.R. § 1.97

This Information Disclosure Statement is being filed before the mailing of the first Office Action on the merits. Thus, pursuant to § 1.97(b)(3), no fee is required.

Information Cited

Applicants hereby make of record in the above-identified application the information listed on the attached form PTO/SB/08a. The order of presentation of the references should not be construed as an indication of the importance of the references.

Copies of the listed foreign and non-patent literature documents are attached. Copies of the U.S. patent publications are not enclosed.

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art." If the Examiner applies any of the documents as prior art against any claim in the application and Applicants determine that the cited documents do not constitute "prior art" under United State law, Applicants reserve the right to present to the office the relevant facts and law regarding the appropriate status of such documents.

Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

Remarks

It is respectfully requested that:

1. The Examiner consider completely the cited information in reaching a determination concerning the patentability of the present claims;
2. The enclosed form PTO/SB/08a be signed by the Examiner and returned to applicants to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application.

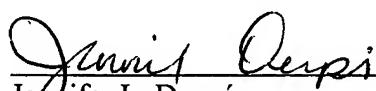
3. The citations for the information be printed on any patent which issues from this application.

An early and favorable action is hereby requested.

The Commissioner is hereby authorized to charge Deposit Account No. 07-1074 for any fees which may be due. A duplicate copy of this paper is enclosed.

Respectfully submitted,

March 25, 2005



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Cambridge, MA 02142
Tel.: (617) 768-6523

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Substitute for form 1449A/PTO		Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>		Application Number	10/814,025
		Filing Date	March 31, 2004
		First Named Inventor	Rasmussen et al.
		Art Unit	1636
		Examiner Name	Sullivan, Daniel M.
Sheet	1	of	8
		Attorney Docket Number	GC22.4-CON2

U.S. PATENT DOCUMENTS

FOREIGN PATENT DOCUMENTS

Examiner Signature		Date Considered	
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This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Substitute for form 1449B/PTO		Complete if Known			
INFORMATION DISCLOSURE STATEMENT BY APPLICANT					
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				Examiner Name	Sullivan, Daniel M.
				Attorney Docket Number	GC22.4-CON2

NON PATENT LITERATURE DOCUMENTS				
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		AERTS, J.M.F.G. et al., "Glucocerebrosidase, a Lysosomal enzyme that does not undergo oligosaccharide phosphorylation", Biochimica et Biophysica Acta, 1988, pp. 303-308.		T ²
		BERGH, M. et al., "Processing and Glycosylation of Human Glucocerebrosidase Expressed in Insect Cells and in Chinese Hamster Ovary Cells", Absts. Paper. Am. Chem. Soc. 200 th Meet. BIOT 109, 1990.		
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		BRADY, R.O. et al., "Demonstration of a Deficiency of Glucocerebroside-cleaving Enzyme in Gaucher's Disease", J. Clin. Invest., 1966, Vol. 45, Issue 7, pp. 1112-1115.		
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		BRADY, R.O. et al., "Modifying Exogenous Glucocerebrosidase for Effective Replacement Therapy in Gaucher Disease", J. Inher. Metab. Dis., 1994, Vol. 17, pp. 510-519.		
		BRADY, R.O. et al., "Status of Enzyme Replacement Therapy for Gaucher Disease", Birth Defects: Original Article Series, 1980, Vol. XVI, No. 1, pp. 361-368.		
		BRADY, R.O. et al., "The Metabolism of Glucocerebrosides. I. Purification and Properties of a Glucocerebroside-Cleaving Enzyme From Spleen Tissue", J. Biol Chem., 1965, Vol. 240, No. 1, pp. 39-43.		
		BRADY, R.O., "The Sphingolipidoses", The New England Journal of Medicine, 1966, Vol. 275, Issue 6, pp. 312-317.		

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		BUTTERS, et al., "Isolation and Characterization of Mosquito Cell Membrane Glycoproteins", <i>Biochimica et Biophysica Acta</i> , 1981, Vol. 640, pp. 655-671.			
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		CREIGHTON, T.E., "Disulfide Bond Formation in Proteins", <i>Methods in Enzymology</i> , 1984, Vol. 107, pp. 305-329.			
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		FRESHNEY, R.I., "Culture of Animal Cells, A Manual of Basic Technique", Alan R. Liss, Inc. New York, Second Edition, p. 69.			
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		FURBISH, F.S. et al., "Uptake and Distribution of Placental Glucocerebrosidase in Rat Hepatic Cells and Effects of Sequential Deglycosylation", <i>Biochimica et Biophysica Acta</i> , 1981, Vol. 673, pp. 425-434.			

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First Named Inventor	Rasmussen et al.
Art Unit	1636
Examiner Name	Sullivan, Daniel M.

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		FURBISH, F.S. et al., "Enzyme replacement therapy in Gaucher's disease: Large-scale purification of glucocerebrosidase suitable for human administration", Proc. Natl. Acad. Sci. USA, 1977, Vol. 74, No. 8, pp. 3560-3563.	
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT				<i>Application Number</i>	10/814,025
<i>(Use as many sheets as necessary)</i>				<i>Filing Date</i>	March 31, 2004
				<i>First Named Inventor</i>	Rasmussen et al.
				<i>Art Unit</i>	1636
				<i>Examiner Name</i>	Sullivan, Daniel M.
Sheet	5	of	8	<i>Attorney Docket Number</i>	GC22.4-CON2

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		KAUFMAN, R.J. et al., "Expression, Purification, and Characterization of Recombinant γ -Carboxylated Factor IX Synthesized in Chinese Hamster Ovary Cells", The Journal of Biological Chemistry, 1986, Vol. 261, No. 21, pp. 9622-9628.		
		KOHN, D.B. et al., "Human Glucocerebrosidase Gene Transfer by Retroviral Vectors", Ped. Res., 1989, Vol. 25, No. 4, Part 2, 852, p. 145a.		
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		MAIORELLA, B. et al., "Optimized PH Control for Antibody Production", ACS National Fall Meeting, Miami, abstract, 1989.		
		MARTIN, B.M., "Glycosylation and Processing of High Levels of Active Human Glucocerebrosidase in Invertebrate Cells Using a Baculovirus Expression Vector", DNA, 1988, Vol. 7, No. 2, pp. 99-106.		
		MILLER, W.M. et al., "Effects of Dissolved Oxygen Concentration on Hybridoma Growth and Metabolism in Continuous Culture", J. Cell. Physiol., 1987, Vol. 132, pp. 524-530.		
		MURRAY, G.J. et al., "Lectin-Specific Targeting of Lysosomal Enzymes to Reticuloendothelial Cells", Meth. in Enzymol., 1987, Vol. 149, pp. 25-42.		

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		NORDIN, J.H. et al., "A Comparative Study of the Size-Heterogeneous High Mannose Oligosaccharides of Some Insect Vitellins", Biochem. Physiol., 1984, Vol. 798, No. 3, pp. 379-390.	
		PEABODY, D.S. et al., "Termination-Reinitiation Occurs in the Translation of Mammalian Cell mRNAs", Molecular and Cellular Biology, 1986, Vol. 6, No. 7, pp. 2695-2703.	
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		PENTCHEV, P.G. et al., "Isolation and Characterization of Glucocerebrosidase from Human Placental Tissue", J. Biol Chem, 1973, Vol. 248, No. 15, pp. 5256-5261.	
		PUGH, G.G., "The Role of Oxygen Consumption Rate in Bioreactor Process Control", Bio/Technology, 1988, Vol. 6, pp. 524-526.	
		REINER, O. et al., "Efficient <i>In Vitro</i> and <i>In Vivo</i> Expression of Human Glucocerebrosidase cDNA", DNA, 1987, Vol. 6, No. 2, pp. 101-108.	
		REUVENY, S. et al., "Factors affecting cell growth and monoclonal antibody production in stirred reactors", J. Immunolog. Meth., 1986, Vol. 86, pp. 53-59.	
		RHODES, M., "Large-Scale Production of Proteins from Mammalian Cells", Biotechnology, 1988, Vol. 6, pp. 518-526.	
		SIGMA CELL CULTURE REAGENTS, Catalog/Price List, 1990 pp. 224-225 and pp. 220-221	
		SORGE, J. et al., "Molecular cloning and nucleotide sequence of human glucocerebrosidase cDNA", Proc. Natl. Acad. Sci. USA, 1985, Vol. 82, pp. 7289-7293.	
		SORGE, J. et al., [Correction notice], Proc. Natl. Acad. Sci. USA, 1986, Vol. 83, p. 3567.	

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		SORGE, J. et al., "Complete correction of the enzymatic defect of type I Gaucher disease fibroblasts by retroviral-mediated gene transfer", Proc. Natl. Acad. Sci. USA, 1987, Vol. 84, pp. 906-909.		
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		TREMBLAY, P.J. et al., "Transgenic Mice Carrying the Mouse Mammary Tumor Virus ras Fusion Gene: Distinct Effects in Various Tissues", Molecular and Cellular Biology, 1989, Vol. 9, No. 2, pp. 854-859.		
		TRIVEDI, L.S. et al., "Normal and Warfarin-Resistant Rat Hepatocyte Metabolism of Vitamin K 2,3-Epoxide: Evidence for Multiple Pathways of Hydroxyvitamin K Formation", Arch. Biochem Biophys., 1988, Vol. 264, pp. 67-73.		
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		Van WEZEL, A.L. et al, "Large Scale Cultivation of Animal Cells in Microcarrier Culture", Process Biochemistry, 1978, pp. 6-8.		

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<p>Filing Date</p>		<p>March 31, 2004</p>			
<p>First Named Inventor</p>		<p>Rasmussen et al.</p>			
<p>Art Unit</p>		<p>1636</p>			
<p>Examiner Name</p>		<p>Sullivan, Daniel M.</p>			
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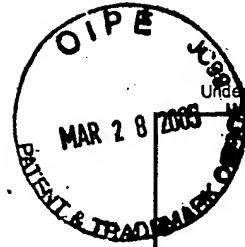
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